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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,876	02/22/2002	Brian Robert Walker	674543-2001.6	2514
20999	7590	09/13/2004		
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151				
			EXAMINER CRIARES, THEODORE J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/080,876	Applicant(s) WALKER ET AL.	
	Examiner Theodore J. Criares	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 14-22 ARE PRESENTED FOR EXAMINATION

Applicant's arguments filed May 19, 2004 and the Declarations of Brian R.

Walker and Jonathan R. Seckl have been fully considered but they are not persuasive.

Applicant argues that there is sufficient compounds that are known inhibitors of 11 beta-hydroxysteroid dehydrogenase to those of ordinary skill in the art. The declarants aver that the skilled artisan would not have required any undue experimentation to practice the claimed invention and incorporate the references cited in the application as evidence thereof. However, a review of the accompanying remarks indicates that the compounds as taught in the references are unpredictable.

In the Monder and White article, at page 199, second full paragraph, it is disclosed that the inhibitory effect between steroids differs between tissues.

Applicant's claims are drawn to a method of reducing circulating fatty acids in adipose tissue in a patient. The patient, as set forth in claims 19-22, can be one suffering from obesity, insulin resistant, or both. There is a lack of guidance in the references submitted by the applicant that one of ordinary skill in the using any one of the compounds taught in the cited literature would be able to know that the compounds taught therein were capable of reducing circulating fatty acids in said patients without undue experimentation. As stated above the compounds in Table IV of the Moner and White reference have different activity in different tissues. One of ordinary skill in the art would have to choose, only after undue experimentation which of the compounds will have the desired effect on the specific tissue claimed. The reference stated above

clearly states that here are different criteria to which compounds have the inhibitory effect. See page 195 wherein it is stated:

“Steroids devoid of oxygen at C-11 are generally not inhibitors, or inhibit oxidation poorly.”

Therefore, the rejection under 35 U.S.C. 112, first paragraph is deemed proper since not all inhibitors are known to act on various tissues effectively. Applicant's one compound does not support the variety of compounds within the claims without further undue experimentation by the skilled artisan. The rejection under 35 USC § 112 is *deemed proper and restated herein.*

The Terminal Disclaimer filed May 19, 2004 in the subject application has been accepted by the United States Patent Office.

Claim Rejections - 35 USC § 112.

Applicant's claims are drawn to a method of reducing circulating fatty acids (CLAIMS 14-20) and treating obesity, insulin resistance or obesity and insulin resistance (claims 21 and 22) by administering a compound which inhibits reductase activity of 11-Beta HSD1

Claims 14-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound carbenoxolone compound does not provide enablement for all compounds which inhibit the reductase activity of 11-Beta-hydroxysteroid dehydrogenase in adipose tissue. There is a lack of compounds which would enable the skilled artisan to practice the invention. Only one compound has been identified by the applicants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

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invention commensurate in scope with these claims 14 and 15. Applicants' specification only identifies one compound which has the claimed activity, i.e. carbenoxolone.

Claims 16 and 17 are rejected since they read on rejected claims 14 and 15.

Therefore, applicants' generic claims 14, 15 and 18-22 are deemed to be beyond the scope of the enabled disclosure in the specification.

The prosecution of this application will be advanced if claims 16 and 17 are incorporated into claims 14, 15 and 18-22.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

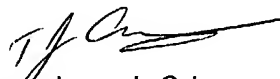
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Criares
Primary Examiner
Art Unit 1617

TJC
9/7/04